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23599 7590 11/08/2010

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
GOON, SCARLETT Y	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 11/08/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,345	07/14/2006	Johannes Reinmuller	WEICKM-0061	2694

TITLE OF INVENTION: COMPOSITION FOR TREATING INFLAMMATORY DISEASES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	02/08/2011

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

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Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)

(Signature)

(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,345	07/14/2006	Johannes Reinmuller	WEICKM-0061	2694

TITLE OF INVENTION: COMPOSITION FOR TREATING INFLAMMATORY DISEASES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	02/08/2011

EXAMINER	ART UNIT	CLASS-SUBCLASS
GOON, SCARLETT Y	1623	514-054000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☐ Issue Fee

☐ Publication Fee (No small entity discount permitted)

☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

☐ A check is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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10/586,345	07/14/2006	Johannes Reinmuller	WEICKM-0061	2694

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Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 145 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 145 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/586,345	REINMULLER ET AL.	
	Examiner	Art Unit	
	SCARLETT GOON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *6 October 2010*.

2. ☒ The allowed claim(s) is/are *1-10,12,13,23 and 25*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 16 July 2010
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/SCARLETT GOON/	/Shaojia Anna Jiang/
Examiner, Art Unit 1623	Supervisory Patent Examiner, Art Unit 1623

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

On 15 October 2010, a proposed amendment in condition for allowance was discussed with Mr. Csaba Henter, Applicants' attorney, in a telephone interview. Authorization for this examiner's amendment was given in a telephone interview with Mr. Csaba Henter on 19 October 2010.

The application has been amended as follows:

- Claims 1, 5 and 25 have been amended, as listed below.
- Claims 22 and 24 have been cancelled, as listed below.
- Note: For those claims that are neither amended nor canceled as indicated in this Examiner's Amendment, see the amendment filed on 6 October 2010.

1. (Currently Amended) A method for treating an inflammatory skin or mucous membrane disease, comprising administering intradermally to a subject in need thereof an effective amount of hyaluronic acid in crosslinked form, which is not administered in conjunction with a penetration-promoting agent,

wherein the inflammatory skin or mucous membrane disease is ~~pruritus, prurigo, urticaria, psoriasis, psoriasis vulgaris, vitiligo,~~ a viral skin disease which leads to wart formation, verruca vulgaris, or Condylomata accuminata~~, rosacea, perioral dermatitis, or a chronic or acute ulceration of the skin~~.

5. (Currently Amended) A method for treating an inflammatory skin or mucous membrane disease, comprising administering intradermally to a subject in need thereof an effective amount of a mixture comprising crosslinked and uncrosslinked hyaluronic acid,

wherein the inflammatory skin or mucous membrane disease is ~~atopic dermatitis, eczema, seborrheic or microbial eczema, pruritus, prurigo, urticaria, red lichen, psoriasis, psoriasis vulgaris, vitiligo,~~ a viral skin disease which leads to wart formation, verruca vulgaris, or Condylomata accuminata~~, rosacea, perioral dermatitis, acne, acne vulgaris, acne conglobata, or a chronic or acute ulceration of the skin~~.

22. (Cancelled)

24. (Cancelled)

25. (Currently Amended) A method for treating an inflammatory skin or mucous membrane disease, comprising administering intradermally to a subject in need

thereof an effective amount of a mixture comprising crosslinked and uncrosslinked hyaluronic acid, wherein the uncrosslinked hyaluronic acid is

(a) short-chain hyaluronic acid having an average molecular weight (weight-average) up to 50 kD, or

(b) a mixture of long-chain hyaluronic acid having an average molecular weight (weight-average) of at least 200 kD, and short-chain hyaluronic acid having an average molecular weight (weight-average) up to 50 kD,

wherein the inflammatory skin or mucous membrane disease is ~~atopic dermatitis, eczema, seborrheic or microbial eczema, pruritus, prurigo, urticaria, red lichen, psoriasis, psoriasis vulgaris, vitiligo,~~ a viral skin disease which leads to wart formation, verruca vulgaris, or Condylomata accuminata~~, rosacea, perioral dermatitis, acne, acne vulgaris, acne conglobata, or a chronic or acute ulceration of the skin~~.

Information Disclosure Statement

The information disclosure statement (IDS) dated 16 July 2010 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. Accordingly, it has been placed in the application file and the information therein has been considered as to the merits.

DETAILED ACTION

Applicants' Amendment and Remarks filed on 6 October 2010, in which claims 11, 14-21 and 26 were cancelled, and claims 1, 5 and 25 are amended to change the scope and breadth of the claims, is acknowledged.

In view of the Examiner's amendment above, claims 1-10, 12, 13, 23 and 25 are pending in the instant application.

The elected species of a viral skin disease which leads to wart formation, as the single disclosed species for an inflammatory skin or mucous membrane disease, has been carefully reviewed and is seen to be allowable. In view of the allowability of the elected species for a viral skin disease which leads to wart formation, the requirement for a species election as set forth in the Office Action mailed 27 August 2008, insofar as it still pertains to the pending claims, is hereby withdrawn. The search has been extended to include the full scope of the claimed method for treating an inflammatory skin or mucous membrane disease, specifically, those related to warts, as set forth in independent claim 1, 5 and 25. The search has also been extended to include the presence of additional components in the administered composition of the claimed method. The full scope of the instant pending claims is found to be allowable.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: The instantly claimed methods, as recited in the instant claims, are not seen to be taught or fairly suggested in the prior art, as discussed below.

Applicants' amendment and arguments, filed 6 October 2010, and the Examiner's amendment above, with respect to the rejection of claims 1-3, 9, 11 and 26 under 35 USC § 102(b), as being anticipated by DE 10209966 A1 to Reinmüller, have been fully considered and are persuasive because Reinmüller does not expressly disclose a method for treatment of a viral skin disease which leads to wart formation, verruca vulgaris, or Condylomata accuminata, as recited in the instant claims. This rejection has been **withdrawn**.

Applicants' amendment and arguments, filed 6 October 2010, and the Examiner's amendment above, with respect to the rejection of claims 5, 6 and 25 under 35 USC § 103(a), as being unpatentable over DE 10209966 A1 to Reinmüller, as applied to claims 1-3, 9, 11 and 26, have been fully considered and are persuasive because Reinmüller does not expressly disclose a method for treatment of a viral skin disease which leads to wart formation, verruca vulgaris, or Condylomata accuminata, as recited in the instant claims. This rejection has been **withdrawn**.

Applicants' amendment and arguments, filed 6 October 2010, and the Examiner's amendment above, with respect to the rejection of claim 4 under 35 USC § 103(a), as being unpatentable over DE 10209966 A1 to Reinmüller, as applied to claims 1-3, 9, 11 and 26, further in view of U.S. Patent No. 4,713,448 to Balazs, have been

fully considered and are persuasive because Reinmüller does not expressly disclose a method for treatment of a viral skin disease which leads to wart formation, verruca vulgaris, or Condylomata accuminata, as recited in the instant claims. The teachings of the Balazs '448 patent do not cure the deficiencies of Reinmüller. This rejection has been **withdrawn**.

Applicants' amendment and arguments, filed 6 October 2010, and the Examiner's amendment above, with respect to the rejection of claims 12 and 13 under 35 USC § 103(a), as being unpatentable over DE 10209966 A1 to Reinmüller, as applied to claims 1-3, 9, 11 and 26, further in view of journal publication by Stanberry, have been fully considered and are persuasive because Reinmüller does not expressly disclose a method for treatment of a viral skin disease which leads to wart formation, verruca vulgaris, or Condylomata accuminata, as recited in the instant claims. The teachings of Stanberry do not cure the deficiencies of Reinmüller. This rejection has been **withdrawn**.

Applicants' amendment and arguments, filed 6 October 2010, and the Examiner's amendment above, with respect to the rejection of claims 1-4, 9 and 11-13 under 35 USC § 103(a), as being unpatentable over PG Pub No. US 2004/0136925 A1 to Petrigni *et al.* (of record), in view of U.S. Patent No. 4,716,224 to Sakurai *et al.*, have been fully considered and are persuasive because Petrigni *et al.* do not expressly disclose a method for treatment of a viral skin disease which leads to wart formation, verruca vulgaris, or Condylomata accuminata, as recited in the instant claims. The

teachings of the Sakurai '224 patent do not cure the deficiencies of Petrigni *et al.* This rejection has been **withdrawn**.

Applicants' amendment and arguments, filed 6 October 2010, and the Examiner's amendment above, with respect to the rejection of claim 23 under 35 USC § 103(a), as being unpatentable over PG Pub No. US 2004/0136925 A1 to Petrigni *et al.* (of record), in view of U.S. Patent No. 4,716,224 to Sakurai *et al.*, as applied to claims 1-4, 9 and 11-13, further in view of journal publication by Sterling *et al.* have been fully considered and are persuasive. Petrigni *et al.* only disclose a method for the treatment of pathological cutaneous diseases, such as eczema or *acne vulgaris*. Although Sterling *et al.* teach that a viral disease leading to wart formation is a cutaneous disease, it is known that cutaneous diseases have different mechanisms of action and different etiologies. Thus, it is not readily apparent to one of ordinary skill in the art that a method for treatment of cutaneous diseases relating to eczema or acne is directly applicable to the treatment of viral disease leading to wart formation. Furthermore, as noted in MPEP § 2144.08 [R-6], the fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) ("The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious."); *In re Jones*, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992) (Federal Circuit has "decline[d] to extract from *Merck & Co. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir. 1989)] the rule that... regardless of how broad, a disclosure of a chemical genus

renders obvious any species that happens to fall within it."). See also *In re Deuel*, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995). This rejection has been **withdrawn**.

Applicants' amendment and arguments, filed 6 October 2010, and the Examiner's amendment above, with respect to the rejection of claims 1-4, 9, 11-13 and 23 under 35 USC § 103(a), as being unpatentable over U.S. Patent No. 5,914,322 to Falk *et al.*, in view of U.S. Patent No. 4,716,224 to Sakurai *et al.*, in view of U.S. Patent No. 6,455,066 B1 to Fischer *et al.*, have been fully considered and are persuasive. The Falk '322 patent teaches a topical composition for the treatment of warts comprising a therapeutically effective non-toxic amount of a drug which inhibits prostaglandin synthesis carried in hyaluronic acid in an amount sufficient to facilitate the drug's penetration through the skin. Thus, the Falk '322 patent teaches that hyaluronic acid is used as a skin penetration agent. While the Fischer '066 patent teaches that it may be advantageous to administer drugs to the skin via an intradermal route, one of ordinary skill in the art would not have been motivated to include the hyaluronic acid from the drug composition of the Falk '322 patent when using the intradermal route as a skin penetration enhancer would not be necessary via the intradermal route. This rejection has been **withdrawn**.

The remaining closest prior art to the instantly claimed invention is PG Pub No. US 2005/0137164 A1 to Arkin *et al.* (PTO-892, Ref. A), which discloses a topical pharmaceutical composition comprising a NSAID for the treatment of skin diseases and

disorders, including genital warts (paragraph 0036; claim 38). For dermal delivery of the composition, Arkin *et al.* teach that a penetration modifier, such as hyaluronic acid, is included in the pharmaceutical composition (paragraphs 0010-0011; claim 22). The hyaluronic acid is thus used as a penetration modifier to localize the NSAID to the affected layer of the skin. The teachings of Arkin *et al.* differ from that of the instantly claimed invention in that the instant claims are drawn to a method for the treatment of a viral skin disease leading to wart formation wherein the active agent is hyaluronic acid, and the composition is administered intradermally. If one of ordinary skill in the art were to administer the composition disclosed by Arkin *et al.* intradermally for treatment of warts, one of ordinary skill in the art would not have been motivated to also include a penetration modifier, such as hyaluronic acid, because, as taught in U.S. Patent No. 6,455,066 B1 to Fischer *et al.* (of record), intradermal administration is intended to keep the pharmacological effects of the drug localized to the intracutaneous regions of drug penetration and deposition. It is therefore *prima facie* obvious to one of ordinary skill in the art that intradermal administration accomplishes the same task as using a penetration modifier for dermal administration of a drug. Thus, while one of ordinary skill in the art may be motivated to administer the NSAID composition intradermally for treatment of warts, one of ordinary skill in the art would have no motivation to further include hyaluronic acid, a penetration modifier, in the composition when the drug is to be administered intradermally. Thus, the teachings of Arkin *et al.* are not considered to be prior art under either 35 USC § 102 or 35 USC § 103 to one of ordinary skill in the art.

As such, the claimed methods for treating an inflammatory skin or mucous membrane disease, as recited in the instant claims, are seen to be novel and non-obvious over the teachings of the prior art.

Exemplary methods for the treatment of warts are disclosed in the instant Specification, for example, in Example 2. Hence, the instantly claimed methods for the treatment of a viral skin disease which leads to wart formation, verruca vulgaris, or Condylomata accuminata, as recited in the instant claims, are enabled and have sufficient written description in the Specification.

Conclusion

Accordingly, the Examiner's Amendment above is sufficient to place the application in condition for allowance.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-

270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623

/SCARLETT GOON/
Examiner
Art Unit 1623